

# Risk Associated with Electrocardiogram (ECG)

Risk Classification Under Medical Device Rules, 2017 Class C  
(Moderate to High Risk)

## Potential Risks

- Interference from Other Electronic Devices
- Calibration and Maintenance Issues
- Lead Reversal Errors
- Signal noise or artifacts
- Inconclusive Results Leading to Additional Testing
- Slight Risk of Electrical Shock
- Skin Irritation & allergy

## Precautions to be Taken

- Proper Electrode Placement
- Check for Loose or Defective Electrodes
- Minimize Movement
- Control Environmental Interference
- Ensure Proper Machine Calibration

Any adverse event associated with these devices can be reported via following tools:-



Issued in Public Interest:

**INDIAN PHARMACOPOEIA COMMISSION**

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